510(k) Summary of Safety and Effectiveness

MAY 11 2010

BaroSense ACE™ Stapler and Cartridge

BAROSENSE INC.

General Information

Criteria	*Information*
Trade Name	ACE™ Stapler (*Note*: the trademark name is still being finalized and may change from that listed above)
Product Name	ACE Stapler and Cartridge
Catalog/Model Number	Model #F0031 (Stapler) Model #F0007 (Stapler Cartridge)
Common Name	surgical stapler and cartridge
Classification	21 CFR 876.1500 - Endoscope and Accessories; Endoscopic Tissue Approximation Device Class II; Product code: OCW
510(k) Owner	BaroSense, Inc. 3698-C Haven Ave. Redwood City CA 94063
Contact Person	Sheila S. Stevens, PhD Director of Clinical Affairs BaroSense, Inc. sstevens@barosense.com 650-362-6000 (phone) 650-362-0700 (fax)

Summary of Substantial Equivalence

The BaroSense Inc., ACE Stapler and Cartridge (models F0031 and F0007) do not raise any new safety or effectiveness issues and are substantially equivalent to legally marketed delivery and fastener devices that are in commercial distribution, and have been determined to be substantially equivalent to devices in commercial distribution, prior to May 28, 1976.

Date: March 5, 2010

Substantially Equivalent Devices

Manufacturer	*Substantially equivalent device*	*510(k)*
EndoGastric Solutions, Inc. Redmond, WA	StomaphyX™ Endoluminal Fastener and Delivery System	K062875
LSI Solutions Rochester, NY	LSI Solutions Flexible Suture Placement Device	K011016
NDO Surgical, Inc. Mansfield, MA	Plicator GSX™ Suturing System	K073671

Device Description

The ACE™ Stapler is a single use, disposable, surgical stapler used in hospitals or surgery centers for the staple closure of small surface lesions on the wall of the stomach or lower esophagus.

The stapler is supplied non-sterile and is fitted with a sterile, single-use staple cartridge. In use, the stapler is introduced into the patient through the mouth using a disposable endogastric tube (EGT). A flexible endoscope passes through the stapler for gastric tissue visualization. The stapler works in conjunction with a vacuum pump to create a plication [tissue fold] in the GI tract, which is then held in place by means of a double, circular row of titanium staples delivered by the stapler (along with a non- absorbable ring to help reinforce the staple placement in the tissue).

The endogastric tube, flexible endoscope and vacuum pump used with the stapler are all commercially available medical devices and are not supplied with the stapler.

Indications for Use

The BaroSense ACE Stapler is indicated for endoluminal trans-oral tissue approximation and ligation in the gastrointestinal tract.

Bench/Animal Testing

All patient contacting components of the ACE Stapler are composed of materials of known biocompatibility tested to the requirements of ISO 10993. The safety and effectiveness of the device was further established through a series of bench and animal tests. All testing yielded acceptable results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G6(
Silver Spring, MD 20993-0002

MAY 11 2010

Sheila Stevens, Ph.D.
Director, Clinical Affairs
BaroSense, Inc.
3698-C Haven Avenue
REDWOOD CITY CA 94063

Re: K082044
Trade/Device Name: ACE™ Stapler
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCW
Dated: March 5, 2010
Received: March 8, 2010

Dear Dr. Stevens:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

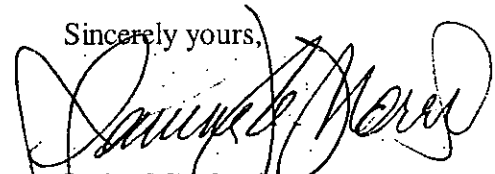
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K082044 pg 1 of 1

Indications for Use Statement

510(k) Number (if known): K082044

Device Name: ACE™ Stapler

Indications for Use: The BaroSense ACE Stapler is indicated for endoluminal trans-oral tissue approximation and ligation in the gastrointestinal tract.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082044